

SAÚDE

EM DESTAQUE

V d A E X P E R T I S E



17 a 21 de janeiro de 2022

LEGISLAÇÃO

NACIONAL

[Decreto Regulamentar Regional n.º 1/2022/A](#)

Região Autónoma dos Açores – Presidência do Governo

Estabelece o regime de atribuição de incentivos à fixação, aplicável ao pessoal médico, na Região Autónoma dos Açores

[Resolução da Assembleia Legislativa da Região Autónoma dos Açores n.º 1/2022/A](#)

Região Autónoma dos Açores – Assembleia Legislativa

Plano Regional de Saúde Mental

REGULAÇÃO

ECONOMIA E TRANSIÇÃO DIGITAL, FINANÇAS E SAÚDE

[Despacho n.º 889/2022](#)

Saúde – Direção-Geral da Saúde

Nomeação dos elementos a coadjuvar o diretor do programa prioritário para a área das hepatites virais

[Despacho n.º 806-A/2022](#)

Finanças e Saúde – Gabinetes da Ministra da Saúde e do Secretário de Estado do Tesouro

Designa os membros para exercer funções no conselho de administração do Hospital de Loures

[Despacho n.º 692/2022](#)

Saúde – Gabinete da Ministra

Designa o presidente e os membros do Conselho Nacional de Saúde Mental

[Publicação para efeitos do artigo 15º-A do Decreto-Lei n.º 176/2006, de 30 de Agosto](#) - pedidos de autorização de introdução no mercado de medicamentos genéricos.

[Notícias](#)

INFARMED

[Comemoração do 29º Aniversário do Infarmed](#)

[EMA dá garantias sobre a utilização de vacinas mRNA durante a gravidez](#)

[Lanadelumab \(Takhzyro\): aprovado financiamento](#)

[29º Aniversário do INFARMED, I.P.](#)

DGS

[Normas e Circulares Normativas](#)

[Norma nº 002/2020 de 16/03/2020 atualizada a 21/01/2022](#) | COVID-19: Procedimentos post mortem

SPMS

[Informação de Detalhe do Procedimento 2022 / 40 | Medicamentos antirretrovíricos para o tratamento da infeção por VIH](#)

[Informação de Detalhe do Procedimento 2022 / 56 | Meios de diagnóstico - imagiologia](#)

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Medicinal Products for Human Use | Other: [Instructor's guide: How to evaluate a CT application - CTIS Training Programme - Module 06 \(updated\)](#)

Medicinal Products for Human Use | News and press releases: [International regulators' recommendations on COVID-19 vaccines and the Omicron variant](#)

Medicinal Products for Veterinary Use | Other: [EU Implementation Guide \(IG\) on veterinary medicines product data in the Union Product Database - Chapter 7: Submission of other post-authorisation data \(updated\)](#)

Medicinal Products for Human Use | Regulatory and procedural guideline: [List of centrally authorised products requiring a notification of a change for update of annexes \(updated\)](#)

Medicinal Products for Veterinary Use | Committee meeting report: [Monthly report on application procedures, guidelines and related documents for veterinary medicines: November 2021](#)

Medicinal Products for Human Use | Committee meeting report: [COMP meeting report on the review of applications for orphan designation: December 2021 \(updated\)](#)

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): [COVID-19 Vaccine Janssen, adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein \(Ad26.COVID-19-S\), COVID-19 virus infection, 11/03/2021, 16, Authorised \(updated\)](#)

Medicinal Products for Human Use | Other: [Quick guide: How to search, view and download a Clinical Trial and a Clinical Trial Application \(authority\) - CTIS Training Programme - Module 15 \(updated\)](#)

Medicinal Products for Human Use | Other: [Instructor's guide: Supervise a CT: corrective measures - CTIS training programme - Module 14 \(updated\)](#)

Medicinal Products for Human Use | Other: [Step-by-step guide: Supervise a CT: corrective measures - CTIS training programme - Module 14 \(updated\)](#)

Medicinal Products for Human Use | Other: [FAQs: Supervise a CT: corrective measures - CTIS training programme - Module 14 \(updated\)](#)

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): [Comirnaty, Single-stranded, 5'-capped messenger RNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike \(S\) protein of SARS-CoV-2, COVID-19 virus infection, 21/12/2020, 19, Authorised \(updated\)](#)

Medicinal Products for Human Use | Other: [FAQs: How to search, view and download a Clinical Trial and a Clinical Trial Application \(authority\) - CTIS Training Programme - Module 15 \(updated\)](#)

Medicinal Products for Human Use | Other: [Instructor's guide: How to search, view and download a Clinical Trial and a Clinical Trial Application \(authority\) - CTIS Training Programme - Module 15 \(updated\)](#)

Medicinal Products for Human Use | Other: [Step-by-step guide: How to search, view and download a Clinical Trial and a Clinical Trial Application \(authority\) - CTIS Training Programme - Module 15 \(updated\)](#)

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Medicinal Products for Human Use | Other: [Step-by-step guide: How to search, view and download a Clinical Trial and a Clinical Trial Application \(sponsors\) - CTIS Training Programme - Module 09](#)

Medicinal Products for Human Use | Other: [Quick guide: How to search, view and download a Clinical Trial and a Clinical Trial Application \(sponsors\) - CTIS Training Programme - Module 09 \(updated\)](#)

Medicinal Products for Human Use | Other: [Instructor's guide: How to search, view and download a Clinical Trial and a Clinical Trial Application \(sponsors\) - CTIS Training Programme - Module 09 \(updated\)](#)

Medicinal Products for Human Use | Other: [FAQs: How to search, view and download a Clinical Trial and a Clinical Trial Application \(sponsors\) - CTIS Training Programme - Module 09 \(updated\)](#)

Medicinal Products for Veterinary Use | [Union Pharmacovigilance Database: webinar on signal detection and analysis, Online, 10:00-13:00 Amsterdam time \(CET\), from 23/11/2021 to 24/11/2021 \(updated\)](#)

Medicinal Products for Human and Veterinary Use | Template or form: [Submission form - Repurposing pilot project for authorised medicines \(updated\)](#)

Medicinal Products for Human Use | Other: [Question and Answers on repurposing pilot project on proposal for framework to support not-for-profit organisations and academia in repurposing authorised medicines \(updated\)](#)

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Medicinal Products for Human Use | Minutes: [CHMP PROM minutes for the meeting on 4 October 2021](#)

Medicinal Products for Human Use | Minutes: [CHMP PROM minutes for the meeting on 3 November 2021](#)

Medicinal Products for Human Use | Agenda: [CHMP PROM agenda for the meeting on 3 November 2021](#)

Medicinal Products for Veterinary Use | [Union Product Database: follow up webinar for marketing authorisation holders, Online, 15:00 - 16:30 Amsterdam time \(CET\), from 25/01/2022 to 25/01/2022 \(updated\)](#)

Medicinal Products for Human Use | Agenda: [CHMP PROM agenda for the meeting on 4 October 2021](#)

Medicinal Products for Human Use | Agenda: [Agenda - CAT agenda of the 19-21 January 2021 meeting](#)

Medicinal Products for Human Use | Other: [Letter of Support for performing registry-based post authorisation safety studies \(PASS\) in Multiple Sclerosis \(MS\) using data of the Big MS Data Network \(BMSD\)](#)

Medicinal Products for Veterinary Use | [Worksharing of variations \(veterinary medicines\)](#)

Medicinal Products for Veterinary Use | [Variations requiring assessment \(veterinary medicines\) \(updated\)](#)

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Medicinal Products for Veterinary Use | [Variations not requiring assessment \(veterinary medicines\) \(updated\)](#)

Medicinal Products for Veterinary Use | [Variations not already listed \(veterinary medicines\) \(updated\)](#)

Medicinal Products for Veterinary Use | [Variations: guidance under Regulation \(EC\) No 1234/2008 and Regulation \(EU\) No 712/2012 \(updated\)](#)

Medicinal Products for Veterinary Use | [Variations: guidance under the Veterinary Medicinal Products Regulation \(Regulation \(EU\) 2019/6\) \(updated\)](#)

Medicinal Products for Veterinary Use | [Variations for veterinary medicines \(updated\)](#)

Medicinal Products for Human Use | Other: [Step-by-step guide: How to evaluate an Additional MSC clinical trial application - CTIS Training Programme - Module 8](#)

Medicinal Products for Human Use | Other: [Step-by-step guide: How to evaluate a Substantial Modification clinical trial application - CTIS Training Programme - Module 8](#)

Medicinal Products for Human Use | Other: [Instructor's guide: Supervise a Clinical Trial: Ad Hoc Assessment - CTIS Training Programme - Module 17 \(updated\)](#)

Medicinal Products for Human Use | Other: [Step-by-step guide: Supervise a Clinical Trial: Ad Hoc Assessment - CTIS Training Programme - Module 17 \(updated\)](#)

Medicinal Products for Human Use | Other: [FAQs: Supervise a Clinical Trial: Ad Hoc Assessment - CTIS Training Programme - Module 17 \(updated\)](#)

Medicinal Products for Human Use | Other: [Quick guide - Part II : How to evaluate an Initial Clinical Trial Application: Assessment and Decision - CTIS Training Programme - Module 08 \(updated\)](#)

Medicinal Products for Human Use | Other: [Quick guide - Part I : How to evaluate an Initial Clinical Trial Application: Assessment and Decision - CTIS Training Programme - Module 08 \(updated\)](#)

Medicinal Products for Human Use | Other: [Quick guide - Decision: How to evaluate an Initial Clinical Trial Application: Assessment and Decision - CTIS Training Programme - Module 08 \(updated\)](#)

Medicinal Products for Human Use | Other: [FAQs: How to evaluate an Initial Clinical Trial Application: Assessment and Decision - CTIS Training Programme - Module 08 \(updated\)](#)

Medicinal Products for Human Use | Other: [Quick guide - Introduction: How to evaluate an Initial Clinical Trial Application: Assessment and Decision - CTIS Training Programme - Module 08 \(updated\)](#)

Medicinal Products for Human Use | Other: [Instructor's guide: How to evaluate an Initial Clinical Trial Application: Assessment and Decision - CTIS Training Programme - Module 08 \(updated\)](#)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: [Recommended submission dates for veterinary medicinal products \(updated\)](#)

Medicinal Products for Human and Veterinary Use | [Scientific publications \(updated\)](#)

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Medicinal Products for Human Use | PRAC recommendation on signal: [Signal assessment report on myocarditis and pericarditis with Spikevax \(previously COVID-19 Vaccine Moderna\) – COVID-19 mRNA vaccine \(nucleosidemodified\)](#)

Medicinal Products for Human Use | PRAC recommendation on signal: [Signal assessment report on myocarditis, pericarditis with Tozinameran \(COVID-19 mRNA vaccine \(nucleosidemodified\) – Comirnaty\)](#)

Medicinal Products for Human Use | [European Medicines Agency \(EMA\) Patients' and Consumers' \(PCWP\) and Healthcare Professionals' \(HCPWP\) Working Parties joint meeting, Online, from 02/03/2022 to 03/03/2022](#)

Medicinal Products for Human Use | Agenda: [CHMP PROM agenda for the meeting on 6 September 2021](#)

Medicinal Products for Human Use | Minutes: [CHMP PROM minutes for the meeting on 6 September 2021](#)

Medicinal Products for Human Use | Minutes: [CHMP PROM minutes for the meeting on 12 July 2021](#)

Medicinal Products for Human Use | Agenda: [CHMP PROM agenda for the meeting on 12 July 2021](#)

Medicinal Products for Human and Veterinary Use | [Management Board meeting: 7 October 2021, European Medicines Agency, Amsterdam, the Netherlands, from 07/10/2021 to 07/10/2021 \(updated\)](#)

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Medicinal Products for Human and Veterinary Use | Minutes: [Minutes of the 113th meeting of the Management Board: 7 October 2021](#)

Medicinal Products for Human Use | [Clinical Trials Information System \(CTIS\) sponsor end user training programme – June 2022, Online, 14:00 – 18:30 Amsterdam time \(CET\), from 20/06/2022 to 23/06/2022](#)

Medicinal Products for Human Use | [Clinical Trials Information System \(CTIS\) sponsor end user training programme – May 2022, Online, 09:00 – 13:30 Amsterdam time \(CET\), from 10/05/2022 to 13/05/2022](#)

Medicinal Products for Human Use | Agenda: [Programme – Clinical Trials Information System \(CTIS\) sponsor end user training programme – June 2022](#)

Medicinal Products for Human Use | Agenda: [Agenda – PDCO agenda of the 18-21 January 2022 meeting](#)

Medicinal Products for Human Use | [Clinical Trials Information System \(CTIS\) sponsor end user training programme – April 2022, Online, 14:00 – 18:30 Amsterdam time \(CET\), from 05/04/2022 to 08/04/2022](#)

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): [Vaxzevria \(previously COVID-19 Vaccine AstraZeneca\)](#), ChAdOx1-SARS-CoV-2, COVID-19 virus infection, 29/01/2021, 18, Authorised (updated)

Medicinal Products for Human Use | Agenda: [Programme – Clinical Trials Information System \(CTIS\) sponsor end user training programme – April 2022](#)

: [Minutes of the CAT meeting 6-8 October 2021](#)

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Medicinal Products for Human Use | [Clinical Trials Information System \(CTIS\) sponsor end user training programme - March 2022, Online, 09:00 - 13:30 Amsterdam time \(CET\), from 01/03/2022 to 04/03/2022](#)

Medicinal Products for Human Use | Agenda: [Programme - Clinical Trials Information System \(CTIS\) sponsor end user training programme - March 2022](#)

Medicinal Products for Human Use | News and press releases: [COVID-19: latest safety data provide reassurance about use of mRNA vaccines during pregnancy](#)

Medicinal Products for Veterinary Use | Agenda: [Agenda - CVMP agenda of the 18-20 January 2022 meeting](#)

Medicinal Products for Human Use | Other: [Article 57 product data \(updated\)](#)

Medicinal Products for Human Use | Agenda: [Agenda - COMP agenda of the 18-20 January 2022 meeting](#)

Medicinal Products for Human Use | [Clinical Trials Information System \(CTIS\) sponsor end user training programme - February 2022, Online, 09:00 - 13:30 Amsterdam time \(CET\), from 15/02/2022 to 18/02/2022](#)

Regulatory | Agenda: [Regulatory science research needs \(RSRN\) launch event \(updated\)](#)

Medicinal Products for Human Use | Agenda: [Programme - Clinical Trials Information System \(CTIS\) sponsor end user training programme - February 2022](#)

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Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): [COVID-19 Vaccine Janssen, adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein \(Ad26.COVID-19-S\), COVID-19 virus infection, 11/03/2021, 15, Authorised \(updated\)](#)

Medicinal Products for Veterinary Use | [Union Product Database: follow up webinar for marketing authorisation holders, Online, from 25/01/2022 to 25/01/2022](#)

Medicinal Products for Human Use | [Clinical Trials Information System \(CTIS\) sponsor end user training programme - January 2022, Online, 14:00 - 18:30 Amsterdam time \(CET\), from 24/01/2022 to 27/01/2022 \(updated\)](#)

Medicinal Products for Human Use | Agenda: [Programme - Clinical Trials Information System \(CTIS\) sponsor end user training programme - January 2022](#)

Medicinal Products for Human Use | Regulatory and procedural guideline: [EudraVigilance registration manual \(updated\)](#)

Medicinal Products for Human Use | [EMA regular press briefing on COVID-19, Online, 16:00 - 16:30 Amsterdam time \(CET\), from 18/01/2022 to 18/01/2022](#)

Medicinal Products for Human Use | Agenda: [Regulatory science research needs \(RSRN\) launch event \(updated\)](#)

Medicinal Products for Human Use | News and press releases: [Meeting highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 10 - 13 January 2022](#)

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Medicinal Products for Human Use | Newsletter: [Human medicines highlights - January 2022](#)

Medicinal Products for Human Use | Minutes: [Minutes of the CAT meeting 6-8 October 2021](#)

COMISSÃO EUROPEIA

[Commission publishes a second Statement on Emerging Health and Environmental Issues](#)

[Draft agenda - Hybrid event: Ensuring Equal Access to All: Cancer in Women - Europe's Beating Cancer Plan \(2 February 2022\)](#)

[Hybrid event - Ensuring Equal Access to All: Cancer in Women - Europe's Beating Cancer Plan \(2 February 2022\)](#)

[Accelerating clinical trials in the EU \(ACT EU\) - Delivering an EU clinical trials transformation initiative](#)

[2022 EU4Health second annual work programme adopted: over €835 million investment in health \(detailed\)](#)

Contactos



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